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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,219	10/19/2005	Kenneth Michlitsch	JM-045 US	8323

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EXAMINER	
NEAL, TIMOTHY J	
ART UNIT	PAPER NUMBER
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,219	MICHLITSCH, KENNETH	
	Examiner	Art Unit	
	Timothy J. Neal	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-40* is/are pending in the application.

4a) Of the above claim(s) *27-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-26, 31-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the amendments received on 1/31/2007. Currently claims 21-40 are pending. Claims 27-30 have been previously withdrawn from consideration as being directed to non-elected material.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 22, 24-26, 33, and 36-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Hannam et al. (US 5,649,959).

Hannam discloses:

21. A device for sealing a puncture tract by forming and extruding an autologous plug within the puncture tract, wherein the puncture tract is disposed within tissue proximal to a vessel, the device comprising: a housing having a lumen (Fig 10) adapted to mix a volume of blood with a blood congealing agent; a closure element (Fig 10 Item 30) configured to be inserted into the puncture tract and to isolate the mixture of the volume of blood and the blood congealing agent from the vessel during formation of the autologous plug from the volume of blood by action of the blood congealing agent; and

a plunger (Fig 10 Item 38) disposed for translation within the lumen to extrude the autologous plug formed within the lumen.

22. The device of claim 21, wherein the housing comprises a second lumen to facilitate placement of a distal end of the device (Fig 11 Item 66).

24. The device of claim 21, wherein the autologous plug formed in the lumen has a length and a form factor that causes the autologous plug to engage tissue surrounding the puncture tract after ejection by the plunger into the puncture tract (Col 12 Line 5).

25. The device of claim 21, wherein the closure element comprises a pledget and thread (Fig 10 Item 30 and 36).

26. The device of claim 25, wherein at least one of the pledget and the thread is biodegradable (Col 7 Line 57).

33. The device of claim 21, wherein the blood congealing agent is introduced into the lumen subsequent to actuation of the closure element (Col 12 Line 66-Col 13 Line 44).

36. The device of claim 21, wherein the blood congealing agent is chosen from the group consisting of thrombin, fibrin, human factor VIII, and combinations thereof (Col 9

Line 22).

37. The device of claim 21, wherein the blood congealing agent comprises a matrix (Col 8 Line 37).

38. The device of claim 37, wherein the matrix is chosen from the group consisting of gauze, biocompatible foam, and spun fiber (Col 8 Line 37).

39. The device of claim 37, wherein the matrix is biodegradable (Col 8 Line 37).

Claims 21-26, 31, 32, and 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey et al. (US 5,545,178).

Kensey discloses:

21. A device for sealing a puncture tract by forming and extruding an autologous plug within the puncture tract, wherein the puncture tract is disposed within tissue proximal to a vessel, the device comprising: a housing having a lumen (Fig 1 Item 64) adapted to mix a volume of blood with a blood congealing agent; a closure element (Fig 1 Item 38) configured to be inserted into the puncture tract and to isolate the mixture of the volume of blood and the blood congealing agent from the vessel during formation of the autologous plug from the volume of blood by action of the blood congealing agent; and a plunger (Fig 1 Item 76) disposed for translation within the lumen to extrude the

autologous plug formed within the lumen.

22. The device of claim 21, wherein the housing comprises a second lumen to facilitate placement of a distal end of the device (Fig 1 Item 72).

23. The device of claim 22, wherein the second lumen is disposed within the plunger (Fig 1 Item 72).

24. The device of claim 21, wherein the autologous plug formed in the lumen has a length and a form factor that causes the autologous plug to engage tissue surrounding the puncture tract after ejection by the plunger into the puncture tract (Fig 5).

25. The device of claim 21, wherein the closure element comprises a pledget and thread (Fig 1 Item 38 and Items 42A and 42B).

26. The device of claim 25, wherein at least one of the pledget and the thread is biodegradable (Col 8 Line 60 and Col 9 Line 35).

31. The device of claim 21, wherein the blood congealing agent is pre-disposed within the lumen (Fig 1 Item 36).

32. The device of claim 31, wherein the blood congealing agent is coated onto an

interior surface of the lumen (Col 10 Line 2).

37. The device of claim 21, wherein the blood congealing agent comprises a matrix (Col 8 Line 25).

38. The device of claim 37, wherein the matrix is chosen from the group consisting of gauze, biocompatible foam, and spun fiber (Col 8 Line 25).

39. The device of claim 37, wherein the matrix is biodegradable (Col 8 Line 25).

40. The device of claim 37, wherein the matrix comprises at least one channel disposed therethrough (Fig 1 Item 36).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey (US 5,545,178) in view of Greenhalgh (U.S. 6,391,037).

Kensey discloses the invention substantially as claimed as stated above. Kensey does not disclose the blood congealing agent comprises a platinum wire; the blood congealing agent comprises a thermo-resistive wire.

Greenhalgh teaches a platinum and thermo-resistive wire (Col 1 Line 52) to clot blood. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Kensey's wound sealing apparatus to include Greenhalgh's platinum and thermo-resistive wires. Such a modification would promote blood clotting.

Response to Arguments

Applicant's arguments filed 1/31/2007 have been fully considered but they are not persuasive.

The Applicant has argued that the references Hannam and Kensey do not disclose an autologous plug. The Examiner contends that the claims, specifically independent claim 21, do not require an autologous plug. The only structures of claim 21 include a housing having a lumen, a closure element, and a plunger. The terms "adapted to" and "configured to" as recited in the claim do not structurally limit the claims beyond what the prior art is capable of doing. The Examiner considers the prior art of Hannam and Kensey to be capable of drawing blood into the lumen so that it may interact with a blood congealing agent to form an autologous plug. The Applicant has not shown any deficiencies in the Examiner's action directed towards the presence of a housing having a lumen, a closure element, and a plunger. The prior art may or may

not be used in the manner disclosed by the Applicant. However, the intended use of the device is given no patentable weight in the instant case because the prior art is capable of performing the functional limitations. The Applicant has also argued that the combination of Greenhalgh with Kensey would not have been obvious because Kensey does not teach an autologous plug. The Examiner disagrees and considers the use of platinum as a blood congealing agent to no be patentable over the prior art. Platinum, as taught by Greenhalgh, is known to be used as a congealing agent.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
3/26/07.